IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

IN RE: ARMODAFINIL PATENT LITIGATION	MDL Docket No. 1:10-2200-GMS
CEPHALON INC. and CEPHALON FRANCE, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	C.A. No. 09-954-GMS REDACTED: PUBLIC VERSION

MYLAN PHARMACEUTICAL INC.'S ANSWERING BRIEF IN OPPOSITION TO PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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I. INTRODUCTION

Cephalon's request for the extraordinary remedy of a temporary restraining order and preliminary injunction enjoining Mylan from lawfully launching its armodafinil product is not warranted in this case. Cephalon, now a wholly-owned subsidiary of generic drug manufacturer and one-time defendant in this action, Teva Pharmaceuticals Industries Ltd. ("Teva"), improperly attempts to extend protection on an alleged invention that was previously disclosed in a long-expired patent covering armodafinil, U.S. Patent No. 4,927,855 ("the '855 patent"). Cephalon alleges that Mylan's proposed generic version of Cephalon's "Nuvigil®" drug containing armodafinil infringes U.S. Patent No. 7,132,570 (the "'570 patent"). However, Cephalon acknowledges that the '570 patent merely claims the most common form (called "Form I") of the prior-known drug molecule armodafinil. (D.I. 263 at 6). Cephalon previously disclosed a method of making crystalline armodafinil and its therapeutic uses, and patented armodafinil for those uses in the '855 patent, which issued on May, 1990. Cephalon's 17 years of marketing exclusivity on this drug expired in 2007, and it should not continue to exclude others from marketing the drug by claiming that it has now "discovered" the most common crystal form claimed in the '570 patent.

The prior art '855 patent inherently anticipates the '570 patent at issue in this case. Cephalon *has presented no experimental evidence* contradicting Mylan's affirmative evidence that the Form I armodafinil crystal claimed in the '570 patent inherently results from following the '855 patent Preparation I prior art process for synthesizing armodafinil ("Preparation I").

REDACTED by the late 1990s and early 2000s, it was well-known in the pharmaceutical development field that it was necessary to identify the different crystalline forms of any identified drug candidate molecule, such as armodafinil, and that there were well-known, routine methodologies for doing so, including, for example, use of

conventional polymorph screening and characterization techniques (such as X-ray powder diffraction ("XPRD")).

Cephalon's motion should be denied for at least five reasons: First, Cephalon's delay in seeking injunctive relief from the Court should, under well-settled equitable principles, by itself result in denial of its motion. Second, Cephalon—not Mylan—bears the burden to establish that Mylan's invalidity defenses lack substantial merit. Notwithstanding that burden and the experimental evidence from four different chemists who carried out the synthesis disclosed in the prior art '855 patent and produced the compound claimed in the '570 patent—REDACTED REDACTED Cephalon utterly failed to present any competing empirical evidence and thus fails to meet its burden of proof on this motion. This evidence also supports Mylan's obviousness argument. Likewise, Third, because Cephalon has not met its burden of demonstrating a likelihood of success on the merits, this Court need not make any further findings on the remaining preliminary injunction factors, but if it did, it would find that Cephalon also fails in its allegations of irreparable harm and other equitable factors. REDACTED

Fourth, entry of the extraordinary relief of an injunction would injure Mylan more than Cephalon. Finally, any delay in Mylan's launch of the first lower-cost generic alternative to branded Nuvigil® harms the public's interest in having early access to lower-cost generics.

II. THE COURT SHOULD DENY THIS MOTION DUE TO CEPHALON'S UNREASONABLE DELAY

Under general equitable principles, a motion for injunctive relief should be denied where the movant improperly delays seeking relief until the last minute, thereby imposing a time for decision that is "probably impossible to achieve except at grave cost . . . to the Court's ability to

decide the case and craft an opinion that would be coherent and responsive to the parties' predictably complex positions." *Union Pac. Corp. v. Santa Fe Pac. Corp.*, Nos. 13778, 13587, 1995 WL 54428, at *3-4 (Del. Ch. Jan. 30, 1995)[1] (denying motion to enjoin $3.85 billion merger on grounds of movants' delay)[2].

Cephalon has known since the Scheduling Conference in early 2011 that Mylan's 30-month stay would expire before trial and before the Court rendered a decision on the merits.

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REDACTED Cephalon nonetheless took no action to protect its interests until April 3, 2012—barely a month before Mylan is permitted to take its approved generic armodafinil product to market—at a time when the only way the Court can fully and fairly consider the merits of Cephalon's application is to put aside the other equally important, longer pending business that fills the Court's crowded docket.

By the time Cephalon finally filed its motion, Cephalon left so little time for decision that the motion can only be decided before May 4th by heroic efforts from the Court. Cephalon's

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[1] Delaware Court of Chancery decisions, often rendered on an expedited basis in the face of a pending transaction, can be instructive as to the application of general equitable principles. *See generally eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 394 (2006) (holding that equitable discretion to grant or deny injunctive relief "must be exercised consistent with traditional principles of equity").

[2] *See also In re Blockbuster Entm't Corp. S'holders' Litig.*, No. 13319, 1994 WL 89011, at *1 (Del. Ch. Mar. 1, 1994) (denying motion for injunctive relief on grounds of movants' two-month delay). *See also, e.g.*, *Cent. Point Software, Inc. v. Global Software & Accessories, Inc.*, 859 F. Supp. 640, 644-45 (E.D.N.Y. 1994) (denying motion for injunctive relief where movants' "extensive delay in bringing [their] motion for a preliminary injunction undercuts any claim of urgency to the preliminary relief[,]" stating that "the period allowed to elapse prior to seeking a preliminary injunction need not rise to the level of laches to bar preliminary injunctive relief.").

[3] All exhibits are contained in Mylan's separately paginated appendix filed pursuant to Local Rule 7.1.4(d) and are cited by page number (*e.g.*, "B____") in this brief. Pursuant to Local Rule 7.1.4(a)(2), all footnotes are presented in 12-point font.

delay is unreasonable since it has known since it filed this action in December of 2009 that Mylan's 30-month stay expires May 4, 2012 and it knew of the FDA's tentative approval of Mylan's ANDA in January of this year. If Cephalon truly believed that Mylan's generic launch would cause irreparable harm, then Cephalon should have moved much sooner, knowing that the 30-month stay would expire before trial. It did not, and thus now burdens this already busy Court with a last-minute motion that will require the Court to put aside its other, equally important business in order to render a decision by the date demanded by Cephalon. Equity rewards the vigilant, *not* the slothful, and for this reason alone Cephalon's motion should be denied.

III. PLAINTIFF CANNOT ESTABLISH LIKELIHOOD OF SUCCESS AND THEREFORE CANNOT OBTAIN INJUNCTIVE RELIEF

"Preliminary injunctive relief is 'an extraordinary remedy' and 'should be granted only in limited circumstances.'" *Kos Pharm., Inc. v. Andrx Corp.,* 369 F.3d 700, 708 (3d Cir. 2004) (citations omitted). A preliminary injunction movant must establish that it is likely to succeed on the merits, that "[it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *AstraZeneca LP v. Apotex, Inc.*, 633 F. 3d 1042, 1049 (Fed. Cir. 2010). "The moving party's failure to show a likelihood of success on the merits must necessarily result in the denial of a preliminary injunction." *Am. Express Related Serv., Inc. v. Sidamon-Eristoff*, 669 F.3d 359**,** 366 (3d Cir. 2012) *citing In re Arthur Treacher's Franchisee Litig.,* 689 F.2d 1137, 1143 (3d Cir.1982).

> A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity, i.e., the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit.

AstraZeneca 633 F. 3d at 1050 (citations omitted) (emphasis added). As this Court has recognized, "[v]ulnerability is the issue at the preliminary injunction stage, while validity is the

issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to the establish invalidity itself." *Arthrex Inc. v. Orthopedics LLC,* No. 02–067 GMS, 2002 WL 818062, at *3 (D. Del. April 30, 2002), *citing Amazon.com, Inc. v. Barnesandnoble.com, Inc.,* 239 F.3d 1343, 1359 (Fed. Cir. 2001) (denying preliminary injunction even though infringement, but not invalidity, was conceded).

Cephalon cannot meet its burden of showing that Mylan's unrebutted invalidity defense "lacks substantial merit" in view of the numerous syntheses following Preparation I of the prior art '855 patent completed by the numerous parties, REDACTED that always resulted in the Form I armodafinil claimed in the '570 patent.

A. Preparation I of the Prior Art '855 Patent Anticipates the '570 Patent

Claimed subject matter is inherently anticipated by a prior art reference if it is necessarily present in and is the natural result of the prior art disclosure, such as Preparation I of the '855 patent. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). Here, Preparation I sets out a straightforward, four-step organic chemistry procedure for the synthesis of armodafinil. (*See* B0002-B0006 (the '855 Patent at col.3 ll 6-55); REDACTED

The final step of Preparation I is a "recrystaliz[ation] from ethanol," and results in "white crystals." (B002-B006 (the '855 Patent at col.3 ll 48-53).) *Every* organic chemist who has prepared armodafinil following Preparation I has, inevitably, produced the Form I armodafinil crystal claimed—improperly—by the patent in suit.[4] Specifically:

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[4] "[A]person following the [prior art] disclosure" obtains the later-claimed product as a "natural result." *See Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001); *see also* Ceph. Br. at 8, citing *Glaxo, Inc., v. Novopharm Ltd.*, 830 F. Supp 871, 874 (E.D.N.C. 1993).

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- Defense expert Dr. Mark Hollingsworth twice followed Preparation I as one of ordinary skill in the art would have done. Both times Form I armodafinil resulted. (B030-B0152 (Hollingsworth Opening Rpt. at 40-92);[5] B0537-B0551 (Rebuttal Expert Rpt. of Dr. Jerry Atwood ("Atwood Rebuttal Rept.") at 8, ¶¶23, 24).)

- Defense expert Dr. Albert Lee also twice followed Preparation I to conclusion—employing the same methodology as Cephalon's experts (who did not complete all of the steps of Preparation I). He too made Form I armodafinil. (B0552-B561 (Rebuttal Expert Rpt. of Albert C. Lee, Ph.D ("Lee Rebuttal Rpt.") at 2-30); B00562-B0576 (Rebuttal Expert Rpt. of Stephen Robie, Ph.D ("Robie Rebuttal Rpt.") at 2-14); B0153-B0244 (Hollingsworth Rebuttal Rpt. at 6-7, nt.17, nt. 12-13, 18, 52-55, 66)); B0537-B0551(Atwood Rebuttal Rept.") at 1, ¶37-

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Even though it is Cephalon that bears the burden on this motion it failed to submit any actual empircal test evidence to rebut the evidence that every chemist who has followed Preparation I of the '855 patent obtained Form I armodafinil. By itself this failure requires denial of Cephalon's preliminary injunction motion. Instead, Cephalon improperly invites this Court to ignore the undisputed testing evidence and instead simply defer to the PTO record, even though that record was formed *ex parte* and contains irrelevant, hearsay declarations (the so-called Blomsma, Peterson and Mallamo declarations at Bourke Exs. 8-10). (D.I. 263 at 2, 8, 10). *See, e.g., Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348, 1359 (Fed. Cir. 2007) ("Our case law consistently provides that a court is never bound by an examiner's findings in an *ex parte* patent application proceeding….. Instead, deference to the decisions of the USPTO takes the form of

the [statutory] presumption of validity.") (citations omitted). Even the decision relied upon by Cephalon explains that "[a]n added burden of deference to the PTO is not required, however, with respect to invalidity arguments based on evidence that the PTO did not consider." *Tokai Corp. v Easton Enters.,* 632 F. 3d, 1358, 1367 (Fed. Cir. 2011) (emphasis added). Here, the PTO did not have before it or consider the unrebutted evidence that Preparation I of the '855 patent results in Form I armodafinil crystals every time the synthesis is conducted.

More importantly, Cephalon never tells the Court that *none* of these declarants actually performed the synthesis in Preparation I of the prior art '855 patent. REDACTED

In other words, the declarants used routine effort, including methods well known in the late 1990s and early 2000s, to identify different crystalline forms of armodafinil using purified armodafinil as the starting point. (B0527-B0536 (*Id*. at 130:15-131:10); B030-B0152 (Hollingsworth Opening Rpt. at 40-43, 98-116); REDACTED Preparation I of the '855 patent describes a process for the actual synthesis of the armodafinil compound, in contrast to the declarations sunmitted to the PTO which describe experiments not related to the synthesis of armodafinil, but rather to the recrystallization of pre-made armodafinil under various conditions that deviated from the '855 patent Preparation I. To the extent that Cephalon's declarants and experts had followed Preparation I, and thus synthesized armodafinil, they would have found that this synthesis inevitably results in the Form I armodafinil claimed in the '570 patent.

Finally, Cephalon intentionally confuses the evidence when it alleges that the '855 patent cannot anticipate the '570 patent claims covering "pharmaceutical compositions" that "consist essentially of" Form I armodafinil because Dr. Hollingsworth in one of his experiments obtained

Form II in addition to Form I. (D.I. 263 at 10.) Dr. Hollingsworth did *not* obtain Form II in addition to Form I when he conducted the Preparation I synthesis of the '855 patent. Preparation I (step (d)) mandates just one "recrystalliz[ation] from ethanol." Dr. Hollingsworth obtained Form I *only* when he conducted the Preparation I single recrystallization from ethanol; *not* a mixture of Form I and Form II as Cephalon incorrectly asserts. (B030-B0152 (Hollingsworth Opening Rpt. at 51, 58).) Dr. Lee's separate syntheses likewise resulted in Form I only without any evidence of any other armodafinil forms being identified.[6] To the extent that Dr. Hollingsworth obtained Form II crystals, that was only later after his Preparation I synthesis had been completed yielding Form I and only during a subsequent "second" recrystallization, not called for by the '855 patent, during which he had accidentally disturbed the solution causing a solid to crash out of the solution. (*Id.* at 59); B00586-B0590 (Hollingsworth Dep. 266-67).).[7]

B. Mylan's Strong Obviousness Defense Also Defeats Cephalon's Motion

A patent claim is invalid if the claimed invention would have been obvious to a person of ordinary skill in the art at the time the invention was made. *Pfizer,* 480 F.3d at 1359-60; 35 U.S.C. § 103(a). Where an ordinarily skilled artisan simply pursues "known options" from a "finite number of identified, predictable solutions," to solve a well-known problem, obviousness under § 103 results. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

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[6] Cephalon also miscontrues the Court's claim construction. The Court has construed "pharmaceutical composition consisting essentially of" based on the parties' agreement as "[a] composition consisting of the specified pharmaceutical active component and optionally unlisted pharmaceutically acceptable ingredients that do not materially affect the basic and novel properties of the specified crystalline pharmaceutical active component." (D.I. 172.) This clearly leaves open the possibility for other ingredients to be present, including other forms, so long as they do not materially affect the basic and novel properties of the Form I. (*See id*.) Thus, it is irrelevant that any other form of armodafinil may be present.

[7] Cephalon has provided no evidence that, even if another form of armodafinil was present in addition to Form I, that such other form would materially affect the basic and novel properties of Form I armodafinil as it relates to the "pharmaceutical composition consisting essentially of" claims.

Mylan's obviousness defense was strong even before Cephalon engaged in discovery abuses and forfeited any right to introduce any evidence of so-called "secondary considerations." (Court Order at D.I. 224.) The '570 patent claims directed to Form I armodafinil are obvious in light of the prior art '855 patent along with well-known, commonly-applied methods and standard pharmaceutical practices used to identify crystals (*i.e.*, polymorphic) forms of drug candidate molecules. REDACTED

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The '855 patent itself specifically identifies ethanol and methanol as solvents to use in purification and crystalization of armodafinil; other typically used solvents were known and identified in standard textbooks, and it is undisputed that Form I is the most easily and commonly formed armodafinil crystal, resulting 95% of the time in standard recrystalization experiments. (B030-B0152 (Hollingsworth Opening Rpt. at 109-111, 113.); B0617-B0623

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A standard polymorph screen would be a necessary step in the research and development for any identified drug candidate molecule, but a person of ordinary skill would have conducted a polymorph screen to find a developable polymorphic form and to meet FDA regulatory compliance requirements.[8] REDACTED

REDACTED In doing so, with respect to armodafinil, that person would have conducted XRPD analyses of the crystalline product obtained from the tests and would have identified and characterized the most thermodynamically stable form of armodafinil, the Form I polymorph. (B030-B0152 (Hollingsworth Opening Rpt. at 40-43, 98-116).)

It is further undisputed that a person of ordinary skill would also be highly motivated to determine the most stable polymorphic form of armodafinil under normal temperature, pressure and humidity conditions and would have sought to determine the most thermodynamically stable polymorphic form of a new drug substance. REDACTED B0152 (Hollingsworth Opening Rpt. at 106-107, 110).) The ordinarily skilled artisan would have been motivated to seek the most stable polymorphic form of armodafinil because that form would not likely convert to a different polymorphic form that could negatively impact a drug product's quality or performance and would reasonably expect to be able to obtain the most

[8] There are numerous prior art references that demonstrate this motivation and knowledge. Just two of these references, Byrn and Yu (B0650-B0671 (Hollingsworth Opening Rpt. Exs. 29 and 30)) demonstrate that a person of ordinary skill in art would have been motivated to conduct polymorphic screening for the armodafinil product of Preparation I. For example, Byrn notes that "[i]nterest in the subject of pharmaceutical solids stems in part from the Food and Drug Administration's (FDA's) drug substance guideline that states 'appropriate' analytical procedures should be used to detect polymorphic, hydrated, or amorphous forms of the drug substance. These guidelines suggest the importance of controlling the crystal form of the drug substance." (B0661-671(Hollingsworth Opening Rpt. Ex. 30, Byrn at 945).) Yu further explains that "[t]he potential impact of changing crystal forms during late-stage drug development, in terms of cost and product delay, justifies systematic and early characterization of polymorphism." (B0650-B0660 (Hollingsworth Opening Rpt. Ex. 29, Yu at 118).)

thermodynamically stable form when conducting a polymorph screen on a particular drug candidate molecule. REDACTED (Hollingsworth Opening Rpt. at 42-43, 106-7, 110); REDACTED

Indeed, the declarations submitted to the PTO by Cephalon illustrate the results from polymorph screening. (*See* Bourke Exs. 8-10.) The vast majority of the trials discussed in Cephalon's declarations produced Form I armodafinil. This evidence reconfirms: (1) that routine polymorph testing would have resulted in Form I, making it obvious; and (2) that the most stable form of armodafinil would have invariably resulted from these routine efforts, including use of polymorph screening. Furthermore, a person having ordinary skill in the art—after identifying various polymorphic forms of a drug substance—would have readily determined which of these polymorphic forms is the most thermodynamically stable. REDACTED REDACTED

Cephalon cannot carry its burden to show that no substantial question of obviousness exists by claiming that a particular crystalline form, or polymorph, of armodafinil be identified or predicted by the prior art, since the particular crystal structures are readily determined by routine testing (*e.g.*, through PXRD). What is required for obviousness is merely that there was a "design, need, or market pressure" to identify and characterize the crystalline forms of armodafinil, and that the means for doing so*, i.e.*, use of polymorphic screening techniques, were known by those of skill in the pharmaceutical arts. *KSR, supra*; *see also In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (Obviousness cannot be avoided simply by showing some degree of unpredictability in the art, so long as there was a reasonable probability of success.). The evidence of record clearly establishes obviousness. The Federal Circuit has held that even if the experimentation might have been costly, lengthy or difficult, yet was a known process that one of ordinary skill in the art would know to conduct, the resulting subject matter (*i.e.*., Form I) is

not inventive. *See Pfizer, Inc*. 480 F.3d at 1367.

Cephalon likewise does not carry its burden by arguing that the prior-art references fail to disclose each claim limitation. Accordingly, there is no requirement, as Cephalon erroneously urges—relying on outdated and questionable pre-KSR lower court cases (D.I. 263. at 11-12)—that the prior art must disclose that armodafinil comes in multiple crystalline forms (polymorphs) as well as the particular atomic and crystalline structure of Form I to make the '570 patent claims invalid as obvious. *See Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1349 (Fed. Cir. 2001). Cephalon incorrectly argues that the prior art must directly and explicitly teach (*i.e.*, anticipate) Form I in order to establish obviousness under § 103. Cephalon improperly conflates the two separate doctrines of invalidity.

The error of Cephalon's argument is magnified by the Federal Circuit's post-KSR decision *In re Kubin*, wherein the Appellant attempted to claim a particular sequence of DNA that it had isolated and characterized using established gene characterization techniques. The Federal Circuit affirmed that the claimed invention was invalid as obvious because even though a limited number of methodologies to isolate NAIL cDNA existed and one of ordinary skill in the art would have had a reason to try these methodologies with a reasonable expectation of success of isolating DNA sequences—notwithstanding that, as in this case, no literature described or identified the particular gene sequence (or the particular crystalline structure of armodafinil) that would be found using that standard methodology. This was because "appellants used conventional techniques . . .to isolate a gene sequence for NAIL." 561 F. 3d at 1356. *Kubin*'s logic applies equally here, since it is undisputed that identifying polymorphic forms are well-

known techniques for identifying at least the commonly occurring crystalline forms of a drug candidate molecule such as armodafinil.[9]

Cephalon also inappropriately relies on the Federal Circuit's decision in *Sanofi-Synthelabo v. Apotex Inc*., which is directed to obviousness in the context of enantiomeric separation. 550 F.3d 1075 (Fed. Cir. 2008) (D.I. 263 at 13.). But the court in *Sanofi-Synthelabo* upheld the patent even though it was prima facie obvious, because the patentee had demonstrated unexpected results – something that Cephalon has not done and is indeed barred from asserting in this case due to its discovery misconduct.[10] (D.I. 224.)

IV. IRREPARABLE HARM AND "BALANCING" FACTORS ARE IRRELEVANT, AND DO NOT SUPPORT PLAINTIFFS

To win this motion Cephalon must establish that it will suffer irreparable harm. *Reebok Int'l Ltd. v. J. Baker, Inc.,* 32 F.3d 1552, 1556 (Fed. Cir. 1994) (preliminary injunction motion may be denied if plaintiff cannot establish either likelihood of success or irreparable harm.)

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[9] The Supreme Court in *KSR* made very clear that the obviousness evaluation must be fact intensive, applying an "expansive and flexible approach" (550 U.S. at 415-419); the Court rejected the use of "rigid and mandatory formulas." (*Id*. at 419). Accordingly, the blind application of any "alleged" hard rule that "a crystal form is non-obvious if the prior art did not suggest the particular structure and form" would be improper. (D.I. 263 at 11, *citing In re Certain Crystalline Cefadroxil Monohydrate*, 15 U.S.P.Q. 2d. 1263 (I.T.C. 1990). Notably, the court in the pre-KSR Bristol Myers crystal patent case relied on the fact that the claimed polymorph was, unlike in this case, extremely difficult to isolate, that "a number of experienced chemists did not obtain the new monohydrate," and that the named inventors "*accidently* obtained the trihydrate that led to the new monohydrate." (*Bristol-Myers Co. v I.T.C.*, (Unpublished), 1989 Westlaw 147230 at 4, 5 (Fed. Cir. 1989 unpublished) Obviousness of the patent claim at issue here depends on the state of the art as of 2000, and other relevant facts pertaining to development and identification of the Form I crystal of armodafinil. These older, unpublished decisions were concerned with the state of the art in 1976, 25 years earlier, relating to a different compound and its different crystallization characteristics. *See id*. at 1267. Simply put, dicta in these older, unpublished, decisions are not binding on this court, are inconsistent with KSR and more recent Federal Circuit cases, were not dispositive to the courts that made the statements and have no relevance to the factual issues relating to the alleged invention at issue.

[10] *Accord*, *Pfizer Inc. v. Apotex Inc.*, 480 F.3d at 1348 (the results of routine testing—in that case routine screening for pharmaceutically acceptable salts—are obvious, not patentable.)

A. Cephalon Will Not Suffer Irreparable Harm And Cephalon Itself Has Argued The Same Against Other Generic Manufacturers

An injury is irreparable only if it cannot be undone through monetary remedies. *eBay v. MercExchange, L.L.C.*, 547 U.S. 388, 390 (2006). Cephalon has not met its burden in showing any irreparable harm. As Cephalon's parent Teva has argued in opposing preliminary injunctions when Teva seeks to introduce a generic drug, the loss of the right to exclude does not constitute irreparable harm. This is because the Supreme Court in *eBay* specifically rejected such categorical rules in considering the propriety of equitable relief. 547 U.S. at 391. Teva made precisely this point in successfully opposing a claim of irreparable injury. (B0892-B0921 (Defendant-Appellees Opp'n to Mot. for Inj. Pending Appeal, *Novartis Pharm. Corp., et al v. Teva Pharm. USA, Inc.,* No. 2007-1542, 14 (Fed. Cir. Sept. 11, 2007).)

In any event, the threat of lost sales or market share would not support a showing of irreparable harm. Again, Teva, Cephalon's parent, has argued before the Federal Circuit:

> [T]his Court has ruled in ANDA cases that lost market share is reparable harm compensable by damages, *Abbott Labs*, 452 F.3 at 1347-48; *Eli Lilly & Co. & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996), and where other district courts have reached decisions consistent with the one below, *see Novartis Corp. v. Teva Pharms. USA, Inc.*, 2007 U.S. Dist. LEXIS 42163 at *89-93 (D.N.J. June 11, 2007); *Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp.*, 984 F. Supp. 239, 263 (D.N.J. 1997).

Teva Non-Confidential Br., *Novartis Pharms. Corp., et al v. Teva Pharms. USA, Inc.,* No. 2007-1542, 15 (Fed. Cir. Sept. 11, 2007) (emphasis added).[11] REDACTED

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[11] *See also Abbott Labs.,* 452 F.3d at 1347 ("Teva argues that any harm that Abbott may suffer could be remedied by monetary compensation."); *see also* B0865-B0891 (Teva Non-Confidential Br., *Altana Pharma AG v. Teva Pharm. USA, Inc.,* No. 2008-1039, 2008 WL 700924, at *52-53 (D.N.J. Feb. 25, 2008) ("Teva offered ample credible evidence that Altana's alleged harms of price erosion, decrease in market share, and loss of profits were reversible, calculable, and compensable.").)

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B. Mylan Will Suffer Hardship If An Injunction Is Entered

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C. An Injunction Will Not Serve The Public's Interest

The public has a strong interest in lower-priced drugs, especially given the increasingly high cost associated with healthcare in the current market. *See Hi-Tech Pharmacal Co., Inc. v. FDA,* 587 F. Supp. 2d 1, 12-13 (D.D.C. 2008) ("The public interest lies in 'in receiving generic competition to brand-name drugs as soon as possible' and 'in reduced prices.'").

The Hatch-Waxman Act was enacted specifically to facilitate earlier market entry of lower-cost generic alternatives to brand-name drugs. (*See* Vandaele Decl. at ¶¶49-50.) This is because of the recognized public interest in quickly bringing lower cost generic drugs to market, which Cephalon's parent company Teva itself has and argued when attempting to market generic products. *Id.; see also Hi-Tech Pharmacal*, 587 F. Supp. 2d at 4, 12; *see also Andrx Pharms., Inc. v. Biovail Corp,* 276 F.3d 1368, 1371 (Fed. Cir. 2002); B0865-B0891 Teva Non-Confidential Br, *Altana Pharma AG v. Teva Pharm. USA, Inc.,* No. 2008-1039, 2008 WL

700924, at *56 (D.N.J. February 25, 2008) ("Congress balanced the public interest in enforcing patent rights against the public interest in lower-cost generic pharmaceuticals when it passed the Hatch-Waxman Act.").

Notably, Cephalon's parent Teva came to this exact same conclusion in a brief it filed in opposition to a motion for a preliminary injunction, arguing that the public interest "favors the entry of generic products to the market" as "[n]o public interest is served by the continued enforcement of an invalid patent [or] by perpetuating increased pharmaceutical prices based on a patent issued for an obvious [product]." (B0865-B0891 (Teva Non-Confidential Br., *Altana Pharma AG v. Teva Pharms. USA, Inc.,* No. 2008-1039, 2008 WL 700924, at *56 (D.N.J. Feb. 25, 2008)*;* B0892-B0921(Teva Non-Confidential Br., *Novartis Pharms. Corp. v. Teva Pharms. USA, Inc..,* No. 2007-1542, 2007 WL 4404152 at *58-59 (Fed. Cir. Nov. 26, 2007)) (arguing that a preliminary injunction would cause irreparable harm to the public who would have to pay more for the branded version of the drug than it would have the generic version during the pendency of the injunction).

V. CONCLUSION AND BOND REQUEST

For all of the above reasons, Cephalon's preliminary injunction motion should be denied.

REDACTED

[15] Fed. R. Civ. Pro. 65(c); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1384-85 (Fed. Cir. 2006) (in affirming a $400 million bond in ANDA case, based on the accused infringer's "'potential lost profits, lost market share and associated costs of relaunch' in the event of wrongful enjoinment." Cephalon failed to address its bond requirement in its opening papers. Should Cephalon oppose Mylan's bond request Mylan respectfully reserves the right to respond.

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CERTIFICATE OF SERVICE

I, John W. Shaw, hereby certify that on April 20, 2012, this document was served on the persons listed below in the manner indicated.

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